

Amendment and Response

Page 6 of 12

Serial No.: 10/691,117

Confirmation No.: 5330

Filed: October 21, 2003

For: SULFONATED STYRENE COPOLYMERS FOR MEDICAL USES

Remarks

The Office Action mailed November 25, 2008 has been received and reviewed. Claims 15-17, 30, 35, and 38-39 having been amended, claim 29 having been canceled herein, and claims 40-48 having been added herein, the pending claims are claims 15-17, 30-32, and 34-48.

Claims 15-17, 30, 35, and 38-39 have been amended to recite, among other things, a polysulfonated block copolymer hydrogel, which is supported by the specification at, for example, paragraph [0077], page 16.

Claim 15 has been further amended to recite proper Markush language.

Claim 39 has been further amended to clarify the recitation of a porous surface comprising paper, fabric, or a combination thereof.

New claim 40 recites a polysulfonated hydrogel that is not chemically crosslinked, which is supported by the specification at, for example, paragraph [0079], pages 16-17. New claim 41 is supported, for example, by originally filed claims 5 and 19. New claim 42 is supported, for example, by originally filed claim 18. New claims 43 and 46 are supported, for example, by originally filed claim 16. New claims 44 and 47 are supported by the specification at, for example, paragraph [0078], page 16. New claim 45 is supported by the specification at, for example, paragraph [0079], pages 16-17. New claim 48 is supported, for example, by the specification at paragraph [0084], page 18, and claim 38.

Reconsideration and withdrawal of the rejections are respectfully requested.

Rejections under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 15-17, 29-32, and 34-39 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner alleged that claim 15 included improper Markush language. Independent claim 15 having been amended, Applicants respectfully submit that the rejection as applied to claims 15-17, 29-32, and 34-38 has been obviated.

Applicants note that the Examiner included claim 39 in the present rejection as allegedly being dependent on a rejected claim. Applicants respectfully bring to the Examiner's attention the fact that claim 39 is an independent claim. Nonetheless, to any extent that the above-referenced rejection similarly applies to independent claim 39, claim 39 has been amended and any rejection thereof has been obviated.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are respectfully requested.

Rejections under 35 U.S.C. §103(a)

The Examiner rejected claims 15-17, 29-30, and 34-39 under 35 U.S.C. §103(a) as being unpatentable over Klier et al. (U.S. Publication No. 2004/0081829). Claim 29 having been canceled, Applicants respectfully traverse the rejection of claims 15-17, 30, and 34-39 (as amended).

"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." M.P.E.P. §706.02(j), quoting *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Applicants respectfully submit that the cited reference fails to expressly or impliedly suggest the invention recited in claims 15-17, 30, and 34-39 (as amended), and further that the Examiner has not presented a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references, as discussed herein below.

For example, the present claims (as amended) recite a method that includes, among other things, forming a water-insoluble coating including at least one salt of a polysulfonated **block copolymer** hydrogel on a porous surface. In contrast to the polysulfonated **block copolymer** hydrogels recited in the present claims, Klier et al. describes "absorbent compositions comprising sulfonated **substantially random interpolymers**" (paragraph [004], page 1; emphasis

added). Thus, Applicants respectfully submit that Klier et al. fails to expressly or impliedly suggest the invention recited in claims 15-17, 30, and 34-39 (as amended).

Further, Applicants respectfully submit that the polysulfonated *block copolymer* hydrogels recited in the present claims differ from the sulfonated *substantially random interpolymers* disclosed by Klier et al. to such an extent that one of skill in the art would not be motivated to modify Klier et al. by using the polysulfonated *block copolymer* hydrogels recited in the present claims, contrary to the allegation by the Examiner (page 5 of the Office Action mailed November 25, 2008).

For example, the present specification describes some of the surprising benefits of using polysulfonated hydrogels such as polysulfonated block copolymer hydrogels:

It has been surprisingly discovered that sulfonated styrene polymers are useful as a hydrogel material that can be used to prepare lacquers or latexes, with or without therapeutic agents, for coating onto other material substrates to yield medical articles useful for treating medical conditions. . . . These hydrogel polymers do not require chemical crosslinking, are soluble in common solvents and can be dehydrated and re-hydrated without the formation of cosmetic defects.

These sulfonated styrene polymeric hydrogels are unique, and given their superior properties relative to chemically cross-linked materials, excellent candidates for use in wound care and other medical applications for at least two very important reasons. The first is related to processing advantages that these materials possess. Sulfonated copolymer hydrogels, such as sulfonated styrene-ethylene-butylene-styrene, sulfonated styrene-ethylene and other copolymers such as sulfonated SIBS, SEPS and SIS are soluble in common organic solvents such as tetrahydrofuran, chloroform, dichloro-methane, and methyl-ethyl ketone. As such, high solids lacquers are easily prepared allowing for the casting of films, coating of articles, and impregnation of fabrics using dipping, painting, or spraying. These sulfonated hydrogels may also be processed to yield latex formulations, thus eliminating the use of organic solvents.

. . .

These sulfonated copolymer hydrogels have chemical structures that allow them to be processed from a solution/lacquer using electrodeposition or electroprocessing. Using this technique, ultrathin fibrous, high surface area device configurations may be created. Devices in the forms of sheets, tubes or other configurations including pouches or spheres may be created. The electroprocessing technique may be carried out with therapeutic agents, including biomolecules, included in the lacquer from which the polymer is spun to create drug delivering polymer strands/fibers. However, in order to fabricate sulfonated styrene polymer hydrogels that incorporate biomolecules, it may be necessary to hydrate the styrene copolymer hydrogel in the presence of an aqueous solution of the biomolecule of interest in order to avoid denaturation of the protein, peptide or the like. However, small, typically synthetic species such as steroids (dexamethasone), antibiotics (tetracyclines/doxycycline, gentamicin), and antineoplastic agents such as paclitaxel or sirolimus may be incorporated into the organic (solvent) solutions of the hydrogel of interest and dip coated, sprayed, painted, or electroprocessed in a straightforward manner. Furthermore, the robustness of these materials allows for them to be press-formed using high pressure into sheet, tube, and other pertinent forms.

Furthermore, these sulfonated styrene polymeric hydrogel materials do not require chemical or radiation crosslinking in order to render them with mechanical properties and characteristics suitable for them to be used in a medical application. Chemical and/or radiation crosslinkable hydrogels, such as poly(vinylpyrrolidinone) or polyethylene oxide, have poor mechanical properties even after crosslinking, thus limiting their applicability in medical articles. For example, when used as wound care materials, chemically cross-linked hydrogels are formed into sheets/films for application as a topical wound dressing product. By virtue of the poor mechanical properties of these materials, they cannot be formed into dressings with the versatility to be used as wound coverings or as wound packing(s), either as free-standing films or as gauze or fabric/material-supported configurations. (Paragraphs [0075]-[0079], pages 16-17).

In contrast to the polysulfonated *block copolymer* hydrogels recited in the present claims, Klier et al. describes "absorbent compositions comprising sulfonated *substantially random*

interpolymers" (paragraph [004], page 1; emphasis added). For at least this reason, Applicants respectfully submit that Klier et al. in fact teaches away from the presently claimed invention. "[A] reference that 'teaches away' from a given combination may negate a motivation to modify the prior art to meet the claimed invention. . . . A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Ormco Corp. v. Align Technology Inc.*, 79 U.S.P.Q.2d 1931, 1938 (Fed. Cir. 2006).

Moreover, Applicants respectfully submit that the description by Klier et al. of the sulfonated substantially random interpolymers further differentiates the interpolymers disclosed by Klier et al. from the polysulfonated **block copolymer** hydrogels recited in the present claims. For example, Klier et al. recite that "[t]he use of the sulfonated substantially random interpolymers-based materials for absorbent and/or superabsorbent applications" (paragraph [0015], page 2). "The term 'superabsorbent polymer' is used herein in the conventional sense in reference to polymeric materials that imbibe fluid and thereby form a swollen hydrogel. That is, a superabsorbent polymer is a hydrogel-forming polymeric gelling agent. In particular, the polymeric gelling agent comprises a substantially water-insoluble, partially neutralized, hydrogel-forming polymer material that is typically prepared from polymerizable, unsaturated, acid-containing monomers and often grafted onto other types of polymer moieties and then slightly **crosslinked** with agents such as, for example, triallyl amine." (Paragraph [0033], page 3; emphasis added).

For at least these reasons, Applicants respectfully submit that the Examiner has failed to present a convincing line of reasoning as to why the artisan would have found the invention recited in claims 15-17, 30, and 34-39 (as amended) to have been obvious in light of the teachings of Klier et al.

For at least the reasons discussed herein above, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for claims 15-17, 30, and 34-39 (as amended) being unpatentable over Klier et al.

The Examiner rejected claims 31-32 under 35 U.S.C. §103(a) as being unpatentable over Klier et al. (U.S. Publication No. 2004/0081829) in view of Wood et al. (U.S. Patent No. 5,429,590). Applicants respectfully traverse the rejection.

Claims 31-32 ultimately depend from claim 15. The deficiencies of Klier et al. as applied to claim 15 (as amended) have been discussed herein above. Further, Applicants respectfully submit that Wood et al. fail to provide that which is missing from Klier et al.

For at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for claim 31-32 being unpatentable over Klier et al. in view of Wood et al.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

New Claims

New independent claim 40 recites a method for controlling biological organisms on a porous surface. The method includes forming a water-insoluble coating on the porous surface, wherein the water-insoluble coating includes at least one salt of a polysulfonated hydrogel that is not chemically crosslinked. Applicants respectfully submit that new independent claim 40 and new dependent claims 41-47 are patentable over the art of record for reasons similar to those discussed herein above for the patentability of claims 15-17, 30-32, and 34-39.

New independent claim 48 recites a method for controlling biological organisms on a porous surface. The method includes forming a water-insoluble coating on a porous surface that is an article selected from the group consisting of a garment, a gas filter, a laboratory work surface, a laboratory wipe, and a wound dressing. The water-insoluble coating includes at least one salt of at least one polysulfonated block copolymer hydrogel blended with at least one non-sulfonated polymer.

Entry and consideration of new claims 40-48 are respectfully requested.

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Page 12 of 12

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Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop RCE, P.O. Box 1450, Alexandria, VA 22313-1450, on this 25th day of February, 2009.

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